DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
5100 Paint Branch Parkway
College Park, Maryland 20740

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Marc H. Bozeman
Hogan & Hartson, LLP
1999 Avenue of the Stars
Suite 1400
Los Angeles, California 90067

Dear Mr. Bozeman:

This is to inform you that the notification, dated October 31, 2006, that you submitted pursuant to 21 U.S.C. 350b(a)(2)(section 413(a)(2) of the Federal Food, Drug, and Cosmetic Act (the Act)), on behalf of your client, Sun Chlorella USA, was filed by the Food and Drug Administration (FDA) on November 1, 2006 and additional information was received on January 17, 2007. Your notification concerned the product called "Sun Chlorella Agaricus", derived from *Agaricus blazei* Murrill (ABM) that your client intends to market as a dietary supplement in the United States.

According to your notification, the recommended conditions of use for "Sun Chlorella Agaricus" are to consume two grams of granules approximately one to three times per day. Your notification further states that "the recommended daily use of the product would result in the consumption of between 1.5 and 4.5 grams of ABM on a daily basis. The package label indicates that individuals with mushroom allergies should refrain from consuming the product."

Under 21 U.S.C. 350b(a), the manufacturer or distributor of a dietary supplement containing a new dietary ingredient that has not been present in the food supply as an article used for food in a form in which the food has not been chemically altered must submit to FDA, at least 75 days before the dietary ingredient is introduced or delivered for introduction into interstate commerce, information that is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such new dietary ingredient will reasonably be expected to be safe. FDA reviews this information to determine whether it provides an adequate basis for such a conclusion. Under 21U.S.C.350b(a)(2), there must be a history of use or other evidence of safety establishing that the new dietary ingredient, when used under the conditions recommended or suggested in the labeling of the dietary supplement, will reasonably be expected to be safe. If this requirement is not met, the dietary supplement is considered to be adulterated under 21U.S.C.342(f)(1)(B) because there is inadequate information to provide reasonable assurance that the new dietary ingredient does not present a significant or unreasonable risk of illness or injury.

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FDA has carefully considered the information in your submission, and the agency has significant concerns about the evidence on which you rely to support your conclusion that a dietary supplement containing "Sun Chlorella Agaricus" will reasonably be expected to be safe.

Your notification states that ABM is also called Himematsutake Extract which is listed by Japanese Health Authorities as "a substance obtained from the mycelium or fruit body of HIME-MATSUTAKE (Agaricus blazei MURR.) or its cultured solution." Moreover, your product, "Sun Chlorella Agaricus", contains Himematsutake Extract along with "chlorella growth factor". However, your notification does not provide compositional information on the cultured solution, the components, or the final product. Therefore, it is unclear how your ingredient is qualitatively or quantitatively similar to the substances described in the information that you rely on for the safety for "Sun Chlorella Agaricus".

For the reasons discussed above, the information in your submission does not provide an adequate basis to conclude that "Sun Chlorella Agaricus", when used under the conditions recommended or suggested in the labeling of your product, will reasonably be expected to be safe. Therefore, your product may be adulterated under 21 U.S.C. 342(f)(1)(B) as a dietary supplement that contains a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury. Introduction of such a product into interstate commerce is prohibited under 21 U.S.C. 331(a) and (v).

Your notification will be kept confidential for 90 days after the filing date of November 1, 2006. After the 90-day date, the notification will be placed on public display at FDA's Docket Management Branch in docket number 95S-0316. Prior to that date, you may wish to identify in writing specifically what information you believe is proprietary, trade secret or otherwise confidential for FDA's consideration.

If you have any questions concerning this matter please contact me at (301) 436-1448.

Sincerely yours,

Linda S. Pellicore

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